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IDSA
Infectious Diseases Society of America

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Marilyn B. Tavenner, RN
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted online: via http://www.regulations.gov

RE: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation, Proposed Rule, [CMS-3244-P]

Dear Acting Administrator Tavenner,

The Infectious Diseases Society of America (IDSA) seeks to engage CMS and other stakeholders in a productive discussion on specific standards for infection control and prevention for inclusion in the Medicare & Medicaid Programs' Conditions of Participation. IDSA represents more than 9,800 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual or drug-resistant microorganisms, people living with HIV and AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza.

Drs. Berwick and Conway explained in a recent commentary that this proposed rule represents a "major revision of the hospital conditions of participation. This new proposal should increase patient-centered care in hospitals and enhance care coordination."[1] Specific to infection control and prevention, they stated that "CMS looks forward to engaging the medical community on what additional quality and safety standards may be needed in the future and how best to include those in the conditions of participation." Therefore, in the spirit of promoting cost-effective, patient-centered care in a culture of safety, we provide the following comments related to infection control and the use of standing orders to improve immunization rates.

[1] Berwick DM, Conway PH. Improving the Rules for Hospital Participation in Medicare and Medicaid. JAMA. 2011;Published online October 18, 2011. doi:10.1001/jama.2011.1611

Infection Control (§482.42):

CMS is proposing to revise the language in the current conditions of participation and remove the requirement for keeping a log of identified problems related to infection control. We agree that advances in infection control surveillance systems have rendered the need for a separate infection control log obsolete. Therefore, we support the removal of this specific requirement while retaining the requirement that infection control officer(s) "develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel."[2]

We would like to take this opportunity to suggest additional quality and safety standards related to infection control that should be considered for inclusion in CMS's Conditions of Participation. We summarize the specific standards below:

- Infection control and prevention programs, as described in current conditions of participation, should also require protocols and staffing for antimicrobial stewardship

- Infection control and prevention programs should be directed by physicians with ID specialty training or infection control certification, (to include antimicrobial stewardship), staffed by certified infection preventionists, and supported by clinical microbiologists and clinical pharmacists with infectious diseases training.

We are advocating for broader recognition of antimicrobial stewardship as an integral component of infection control programs. Antibiotic resistance poses a serious threat to public health, patient care and safety. This issue has reached a critical point, as bacteria are becoming increasingly resistant to available antibiotics, and new drugs are not being developed at a pace necessary to address growing unmet medical needs. Current antibiotics are a precious resource, and the judicious monitoring of the clinically appropriate use of these agents for infection control falls under the responsibility of the Infection Control Team. As infection control officers are charged with developing and implementing "policies governing control of infections and communicable diseases,"[3] ensuring the appropriate use of antimicrobials is a key component of these policies. Antimicrobial stewardship involves coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. Within an Infection Control Team, antimicrobial stewards seek to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the costs of health care for infections, and limit the selection of antimicrobial resistant strains.[4] Therefore, we ask CMS to consider inclusion of "antimicrobial stewardship" as part of the Organization and Policies Standard (§482.42(a)) in the Condition of Participation for Infection Control.

ID specialists are typically internal medicine physicians who have completed an additional two to three years of focused training that qualifies them as experts in the diagnosis, treatment, and prevention of infectious diseases. ID physicians spend a considerable

[2] US Centers for Medicare & Medicaid Services. Proposed rule. http://www.cms.gov/CFCsAndCoPs/06_Hospitals.asp
[3] 42 CFR 482.42 - Condition of participation: Infection control.
[4] http://www.idsociety.org/Stewardship_Policy/

amount of time in the hospital inpatient setting, caring for the most complex patients and typically developing skill sets that include care coordination, physician to physician and team communication, and systems thinking. As such, ID physicians are the appropriate experts to lead infection control and prevention teams in hospitals and to communicate and drive change in physician antimicrobial usage. However, we realize that not all health care facilities have access to ID specialists and must rely on other physicians who have received training in infection control and antimicrobial stewardship to lead their infection control teams. To be clear, we support a multi-disciplinary stewardship team of infection preventionists, pharmacists, and microbiologists but, given the ultimate clinical decision-making involved in prescribing antimicrobial medications for patients, our position is that these teams be physician-led.

Our recommendations are based on current guidelines and clinical evidence as reported in the medical literature. In fact, current guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship, set forth through a joint effort between the IDSA and the Society for Healthcare Epidemiology of America (SHEA), call for the core members of an antimicrobial stewardship program to be infectious disease specialists and a clinical pharmacist with infectious diseases training.[5]

Inclusion of these recommendations in the Conditions of Participation will align with other CMS efforts to promote infection control and antimicrobial stewardship. For example, in the recently released Survey & Certification Focus on Patient Safety and Quality - Draft Surveyor Worksheets, the CMS Office of Clinical Standards & Quality – Survey & Certification Group is testing worksheets that assess Infection Control and Quality Assessment and Performance Improvement (QAPI) related to antimicrobial stewardship.[6] These draft surveys include specific questions to collect data on the presence and effectiveness of antimicrobial stewardship programs in hospitals today.

In addition, the CDC is currently funding the use of a new, electronic-based antibiotic tracking system which will be implemented in approximately 70 hospitals. As part of the National Healthcare Safety Network, this system will support infection control and antimicrobial stewardship as it is intended to "enhance providers' ability to monitor and improve patterns of antibiotic use so that these essential drugs will still be effective in the years to come."[7]

The costs of including antimicrobial stewardship with the Conditions of Participation related to infection control should be more than offset by savings generated. The CDC has published a summary of health economic research focused on employing antimicrobial stewardship programs with results showing significant cost savings.[8] As well, the

[5] Dellit TH, Owens RC, McGowan JE, Gerding DN, Weinstein RA, Burke JP, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship. Clinical Infectious Diseases 2007; 44:159–77.

[6] CMS Policy & Memos to States and Regions - Survey & Certification Focus on Patient Safety and Quality - Draft Surveyor Worksheets. Retrieved Nov. 3, 2011 from https://www.cms.gov/surveycertificationgeninfo/pmsr/itemdetail.asp?itemid=CMS1253109

[7] CDC Press Release. "CDC now tracking antibiotic use in hospitals." Retrieved Nov. 16, 2011 from http://www.cdc.gov/media/releases/2011/p1114_antibiotic_hospitals.html?source=govdelivery

[8] CDC Impact of Antibiotic Stewardship Program Interventions on Costs. Retrieved Nov.3, 2011 from http://www.cdc.gov/getsmart/healthcare/support-efforts/asp-int-costs.html

IDSA/SHEA guidelines on antimicrobial stewardship outline the case for the financial self-sufficiency of such programs.

Finally, in a time where critical drug shortages have become increasingly more common, an effective antimicrobial stewardship program would promote efficient administration of appropriate therapies. In the FDA report on Drug Shortages released in October of this year, (www.fda.gov/DrugShortageReport), antibiotics were the second largest therapeutic drug class to experience shortages, second only to oncology agents. By eliminating the inappropriate use and reducing the over-prescribing of antimicrobial agents, stewardship programs will preserve critical therapies that are in short supply.

Use of Standing Orders to Promote Vaccination (§482.23):

CMS is also proposing changes that would allow hospitals to use standing orders in additional areas with the aim of promoting efficiency and improving patient care. The proposed rule specifically suggests the use of expanded standing orders for immunizations (beyond the currently allowed nurse-initiated influenza and pneumococcal vaccinations) that have clearly established and nationally recognized guidelines (i.e. CDC guidelines endorsed Hepatitis B vaccinations for at-risk newborns). IDSA supports this proposed change as a measure to improve immunization rates for the broader patient population and ultimately support infection control efforts.

Furthermore, to show meaningful promotion of infection control for Medicare beneficiaries, CMS should extend Part B coverage to all ACIP recommended vaccines. Section 1001 of the ACA requires most private health plans to cover all ACIP-recommended vaccines, which enables infection prevention in a significant portion of the population. Currently, Medicare beneficiaries encounter reduced or no access to other preventive vaccines. Therefore, in order to support broad efforts in infection control, CMS should extend coverage to all ACIP recommended vaccines.

IDSA applauds the efforts of CMS to reduce any unnecessary burden under current conditions of participation and to consider for inclusion additional conditions that promote operational efficiency, improved patient safety and better quality of care. We believe our recommendation for the inclusion of antimicrobial stewardship, under the leadership of ID trained physicians, supports better quality of care. We welcome further discussion with CMS and other stakeholders on how to implement the recommendations detailed above. If you have any questions, please feel free to contact Andres Rodriguez, IDSA's Senior Program Officer for Practice & Payment Policy, at 703-299-5146 or arodriguez@idsociety.org.

Sincerely,

Thomas G. Slama MD

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